PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter Fof the Patent Cooperation Treaty)

(PCT Rule 44bis)

| Applicant's or agent's tile reference C05059 | FOR FURTHER ACTION | See item 4 below | |
|---|--|--|--|
| International application No. PCT/AU2005:000539 | International Elling date (day/month/year) 15 April 2005 (15.04.2005) | Priority date (daymentis year) 15 April 2004 (15.04,2004) | |
| International Patent Classification (St See relevant information in Form | h edinon unless older edinon indicated) PCT/ISA/237 | | |
| Applicant RESMED LIMITED | | | |

| ł. | This international preliminary to International Searching Authori | | ter D is issued by the International Bureau on behalf of the |
|----|---|--|--|
| 2. | This REPORT consists of a total | Lot 6 sheets, including this | gover slicet. |
| | In the attached sheets, any refer to the international preliminary | | of the International Searching Authority should be read as a reference pter D instead. |
| ÷. | This report contains indications | relating to the following ite | ms: |
| | Box No. 1 | . Busis of the report | |
| | Box No. II | Priority | |
| | Box No. III | Non establishment of op applicability | vinion with regard to novelty, inventive step and industrial |
| | Box No. IV | Luck of unity of invention | on |
| | Box No. V | | ler Article 35(2) with regard to novelty, inventive step or inclustrial and explanations supporting such statement |
| | Box No. VI | Cortain documents eited | ı |
| | Box No. VII | Certain defects in the m | ternational application |
| | Box No. VIII | Certain observations on | the international application |
| i. | | | esignated Offices in accordance with Rules 44hts.3(e) and 93his.1 but nder Article 23(2), before the expiration of 30 months from the priority |
| | | | |
| | | | Date of issuance of this report 19 October 2006 (19.10.2006) |
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Facsimile No. +41-22-338-82-70 Form PCT/H9/373 (January 2004)

The International Bureau of WIPO 34, chemin des Colombattes

1211 Geneva 20, Switzerland

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| From the: INTERNATIONAL SEARCHING AUTHORITY | | |
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| To: | | PCT |
| Halford & Co. No 1 Market Street SYDNEY NSW 2000 | WR INTERNATI | REC'D 27 JUN 2005 ITTEN OPENIONOS THE ONAL SEARCHRIG AUTHORITICT (PCT Rule 43bis.1) |
| | Date of trailing (day/month/year) | 2 1 JUN 2005 |
| Applicant's or agent's file reference | FOR FURTHER AC | CTION See paragraph 2 below |
| C05059 GD:AM | filing date (day/month/year) | Priority date (day/month/year) |
| anternational appropriate | | 15 April 2004 |
| PCT/AU2005/000539 15 April 2 International Patent Classification (IPC) or both national | | <u>'</u> |
| Int. Cl. 7 A61M 16/08 | | |
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| Applicant RESMED LIMITED et al | | |
| Talestonia in the state of the | | |
| This opinion contains indications relating to the form | ollowing items: | |
| X Box No. 1 Basis of the opinion | | |
| Box No. II Priority | | |
| X Box No. III Non-establishment of opinion w | ith regard to novelty, inventive st | ep and industrial applicability |
| X Box No. IV Lack of unity of invention | | · |
| citations and explanations suppe | 43 bis.1(a)(i) with regard to novel orting such statement | ty, inventive step or industrial applicability: |
| Box No. VI Certain documents cited | | |
| Box No. VII Certain defects in the internation | nal application | 1 |
| Box No. VIII Certain observations on the inte | mational application | |
| 2. FURTHER ACTION If a demand for international preliminary examination Preliminary Examining Authority ("IPEA") except the time IPEA and the chosen IPEA has notified the in Searching Authority will not be so considered. If this opinion is, as provided above, considered to be written reply together, where appropriate, with amen PCT/ISA/220 or before the expiration of 22 months. For further options, see Form PCT/ISA/220. 3. For further details, see notes to Form PCT/ISA, 220. | nat this does not apply where the a ternational Bureau under Rule 66. e a written opinion of the IPEA, the diments, before the expiration of 3. | he applicant is invited to submit to the IPEA a |
| 2. For turner details, see notes to country of the second | | |
| Name and mailing address of the IPEA/AU | Authorized Office | г |
| AUSTRALIAN PATENT OFFICE | AMOD PRAI | OH A N |
| PO BOX 200, WODEN ACT 2006, AUSTRALIA E-mail address: pet@ipaustralia.gov.au | | (02) 6283 2510 |
| Facsimile No. (02) 6285 3929 | Telephone No. (| (2) (20) |

international application No.

PCT/AU2005/000539

| Box | No. l | I Basis of the opinion |
|-----|-------------|--|
| 1. | With | h regard to the language, this opinion has been established on the basis of the international application in the language in ch it was filed, unless otherwise indicated under this item. |
| | | This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)). |
| 2. | Wit clai | th regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the imed invention, this opinion has been established on the basis of: |
| | a. | type of material |
| | | a sequence listing |
| | | table(s) related to the sequence listing |
| | b. | format of material |
| ļ | | in written format |
| | | in computer readable form |
| | c. | time of filing/furnishing |
| | | contained in the international application as filed. |
| | | filed together with the international application in computer readable form. |
| | | furnished subsequently to this Authority for the purposes of search. |
| 3. | | In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filled or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished. |
| 4. | A | dditional comments: |
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international application No.

PCT/AU2005/000539

| Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
|--------------------------------------|--|
| The questions w incustrially appl | thether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be licable have not been examined in respect of: |
| the e | ntire international application |
| X claim | ns Nost 9-33, 35-49, 51-54 |
| because: | |
| the sa | aid international application, or the said claim Nos. |
| ; [| e to the following subject matter which does not require an international preliminary examination (specify): |
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| | , |
| | |
| ! ' ' | description, claims or drawings (indicate particular elements below) or said claims Nos. |
| are s | so unclear that no meaningful opinion could be formed (specify): |
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| | |
| iiii | claims, or said claims Nos. |
| | so inadequately supported by the description that no meaningful opinion could be formed. |
| : | international search report has been established for said claims Nos. |
| | nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the |
| Ad | hministrative Instructions in that: |
| the v | written form has not been furnished |
| | does not comply with the standard |
| | computer readable form has not been furnished |
| the | |
| | does not comply with the standard |
| the wi | e tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply ith the technical requirements provided for in Annex C-bis of the Administrative Instructions. |
| So | re Supplemental Box for further details. |

International application No.

PCT/AU2005/000539

| Box | No. IV | Luck of unity of invention | |
|-----|---------|---|--|
| l. | X | in response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has: | |
| | | paid additional fees | |
| | | paid additional fees under protest | |
| | | X not paid additional fees | |
| 2. | | This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees. | |
| 3. | This . | Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is | |
| | | complied with | |
| | X | not complied with for the following reasons: | |
| l. | p is | Claims 1-8, 34 and 50 are directed to a conduit and its method of use for delivering a supply of gas under sositive pressure comprising a conduit wall which is deformable between an open and collapsed condition. It is considered that the conduit wall which is deformable between an open and collapsed condition comprises a first "special technical feature". | |
| 2. | p | Claims 9-33, 51 and 52 are directed to headgear or a nasal assembly for delivering a supply of gas under positive pressure to a patient comprising a pair of side portions adapted to extend along opposite sides of the patient's head, each side portion defining a conduit. It is considered that each side portion defining a conduit comprises a second special technical feature. | |
| 3. | I i | Claims 35-49, 53 and 54 are directed to a method for constructing headgear comprising mapping the shape of a particular patient's head and forming the headgear in accordance with the mapping of the shape of the head. It is considered that mapping the shape of a particular patient's head and forming the headgear in accordance with the mapping of the shape of the head comprises a third special technical feature. | |
| Te | lations | e abovementioned groups of claims do not share any of the technical features identified, a "technical ship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international ion does not relate to one invention or to a single inventive concept, a priori. | |
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| 4 | . Con | sequently, this opinion has been established in respect of the following parts of the international application: | |
| | | all parts | |
| - | | the parts relating to claims Nos. 1-8, 34, 50 | |

international application No.

PCT/AU2005/000539

| Box No. V Reasoned statement un applicability: citations | der Rule 43bis.1(a)(i) with regard to novelty, and explanations supporting such statement | inventive step or industrial |
|---|---|------------------------------|
| 1. Statement | | |
| Novelty (N) | Claims 3-7 | YES |
| | Claims 1, 2, 8, 34, 50 | NO |
| Inventive step (IS) | Claims 7 | YES |
| • • • | Claims 1-6, 8, 34, 50 | NO |
| Industrial applicability (IA) | Claims 1-8, 34, 50 | YES |
| | Claims | NO |
| | • | |

2. Citations and expianations:

DI US 5765557

D2 US 5538000

Novelty (N) Claims 1, 2, 8, 34, 50

Claims 1, 50

D1 and D2 each disclose all the features of claims 1 and 50. For example, in D1 see:

conduit wall

column 6, lines 22-24 Fig. 1, item 14

first conduit end

column 6, lines 28-29 Fig. 2

second conduit end

column 8, lines 24-26 Fig. 2

conduit passage

column 6, lines 22-24 Fig. 1

conduit passage open condition

column 6, lines 26-37 Fig. 1, item 18

conduit passage collapsed condition

column 6, lines 24-25 Fig. 1, item 16

Claims 2, 8, 34

D1 discloses all the features of claims 2, 8 and 34. In particular, it discloses that the supply of gas urges the conduit wall into the open condition and that at least a portion of the conduit wall has elasticity (column 6, lines 26-28 and 59-62).

The features of the remaining claims are not found in any single document published before the earliest priority date of the claims.

Inventive Step (IS) Claims 1-6, 8, 34, 50

Claims 1, 2, 8, 34, 50

As above.

Claims 3-6

The features added by these claims relate to the manufacture of the conduit wall from materials that are common general knowledge in the art and which cannot be considered as contributing to patentable ingenuity.

The feature of claim 7, wherein the conduit wall has a double wall construction including an inner wall and an outer wall and defining a substantially gas tight space therebetween, were not found in any other document that would be regarded, by a person skilled in the art, as being obvious to combine with either of the above documents.